July 31, 2003

Edwin L. Mongan, III
Manager, Environmental Stewardship
E.I. du Pont de Nemours & Company, Inc.
1007 Market Street
DuPont 6082
Wilmington, DE 19898

Dear Mr. Mongan:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for sec-Butyl urea posted on the ChemRTK HPV Challenge Program Web site on April 3, 2003. I commend E.I. du Pont de Nemours & Company, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that E.I. du Pont de Nemours & Company, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail adresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
sec-Butyl urea

Summary of EPA Comments

The sponsor, E.I. du Pont de Nemours & Company, Inc., submitted a test plan and robust summaries to EPA for sec-Butyl urea (CAS No. 689-11-2) dated January 11, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on April 3, 2003.

EPA believes that the test plan as proposed is not adequately supported. The submitter needs to provide a better basis for its approaches to characterizing health and ecological effects, and for the justification for closed-system intermediate status.

EPA's preliminary comments appear below. EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the sec-Butyl Urea Challenge Submission

Test Plan

1. Physicochemical Properties. For melting point and boiling point, a sublimation temperature was provided in the robust summaries. However, these data are questionable given the measured melting point values identified by EPA for two analogs. Testing is needed for melting point and boiling point using OECD Test Guideline 102 and 103, respectively. For vapor pressure, an estimated vapor pressure was provided. According to HPV Challenge Program guidelines, this endpoint should be measured if the vapor pressure is likely to be $>10^{-5}$ Pa. The submitter should determine vapor pressure using OECD Test Guideline 104.

2. Environmental Fate. EPA disagrees that testing is not necessary for stability in air (photodegradation) and biodegradation. For photodegradation, no data were presented. The submitter needs to estimate the photooxidation potential of sec-butyl urea using AOPWIN. For biodegradation, the submitter provided only an estimate of the biodegradation potential using BIOWIN. Ready biodegradation needs to be measured experimentally following OECD Test Guideline 301.

3. Health Effects. EPA believes that additional justification is needed to support using data on isobutylidene diurea for addressing some of the health effects endpoints. The justification for using the analog is based on the formation of a common metabolite, 1-hydroxyisobutylurea. While this is a reasonable hypothesis, no data are presented on the rate of metabolite formation or whether 100 percent of the parent compound would be metabolized to 1-hydroxyisobutylurea. Thus, one cannot judge whether to ascribe any observed toxicity to the metabolite or to the unmetabolized parent compound. For developmental toxicity, robust summaries need to be submitted on the structurally related alkyl ureas to allow a determination of data adequacy.

4. Ecological Effects. ECOSAR predictions for sec-butyl urea, ECOSAR predictions for an analog (isobutylidene urea), and fish, invertebrate, and algal toxicity tests on this analog are provided to address the ecotoxicity endpoints for sec-butyl urea. No justification for the suitability of the analog was provided and ECOSAR values for sec-butyl urea and the analog differ by a factor of 10. Therefore, these data appear inadequate to satisfy the aquatic toxicity endpoints. Adequate justification needs to be submitted

for the adequacy of analog data; otherwise, acute fish, invertebrate, and algal toxicity testing on sec-butyl urea may be needed.

5. Finally, additional information is necessary to judge the "closed system intermediate" claim. In particular, a process flow diagram should be provided for each site where the material is handled. Although a narrative is provided for the manufacturing site, no description is provided of the processing site other than to say that the customer uses "adequate controls." Some monitoring data are provided but it is not clear what operation/area was monitored. The following statements beg the question about the "closed system intermediate" claim: "Any spills that result from bag loading are washed down to the on-site biological treatment plant. Process wastes from the manufacture of SBU are also treated at the on-site biological treatment plant." Additional details need to be provided about the quantity of spilled material and process wastes and biological treatment efficiency.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.